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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
|-----------------|-------------|----------------------|---------------------|

09/508,967 04/07/00 WAHLGREN

M 45300-59676

000466 HM12/1023  
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EXAMINER

FIELDS, I

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1645  
DATE MAILED:

10/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>09/508,967 | <b>Applicant(s)</b><br>WAHLGREN ET AL. |  |
|                              | <b>Examiner</b><br>Iesha P Fields    | <b>Art Unit</b><br>1645                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) \_\_\_\_\_ is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-17, 21, 24, and 33-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

- |   |  |
|---|--|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 20) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Applicant's amendment received August 8, 2001(Paper No. 12) has been received and entered. Claims 13-17 were amended, claims 1-12, 18-20, 22-23, 25-27, and 28-32 were cancelled, and new claims 33-38 were added, consequently claims 13-17, 21, 24, and 33-38 are pending in the instant application.

#### ***Response to Amendment***

The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

#### ***Claim Rejections - 35 USC § 101***

1. Claims 22-23 rejected under 35 USC § 101 as being directed to non-statutory subject matter have been cancelled. The rejection is therefore moot and will not be further addressed.

***Claim Rejections - 35 USC § 112***

2. Claim 13-17, 21 and 24 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is **withdrawn** in view of Applicant's amendment to the claims.

***Claim Rejections - 35 USC § 102***

3. Claims 13-16 rejected under 35 U.S.C. 102(b) as being anticipated by Rowe et al. is **maintained**.

Applicant's have asserted that Rowe et al. disclose a polypeptide that binds to CR1 in addition to being a parasite ligand. Applicant's have further asserted that the polypeptide of Rowe et al. differs from the claimed invention because the Applicant's polypeptide does not bind to CR1.

Applicant's arguments have been carefully considered but not deemed persuasive.

The claims are drawn to the malaria erythrocyte membrane polypeptide.

As stated previously, Rowe et al. disclose a malaria erythrocyte membrane protein (PfEMP1).

Although the Applicant has argued that the polypeptide in the invention is different from the polypeptide disclosed in the prior art based on binding properties, the claims do not recite this as a limitation.

***Claim Rejections - 35 USC § 103***

4. Claims 13 and 17 rejected under 35 U.S.C. 103(a) as being unpatentable over Rowe et al. in view of Su et al. is **maintained**.

Applicant's have asserted that Rowe et al. disclose a polypeptide that binds to CR1 in addition to being a parasite ligand. Applicant's have further asserted that Su et al. teach of a parasite ligand within the range of 200-350 kDa but fails to describe the function of the polypeptide. Applicant's have further asserted that there is no motivation to combine the teachings of the prior art.

Applicant's arguments have been carefully considered but not deemed persuasive.

The claims are drawn to the malaria erythrocyte membrane polypeptide (PfEMP1) having a weight of about 100-300 kDa.

As stated above, Rowe et al. teach of a malaria erythrocyte membrane protein. Rowe et al. further teach that PfEMP1 is a parasite ligand.

Su et al. teach of a polypeptide which has a weight of about 100-300 kDa (i.e. 250-300 kDa is within the range of "about 100-300 kDa"). Su et al. further teach of the function of such polypeptides (See Especially Discussion Section).

Given that 1) Rowe et al. has taught that binding of infected erythrocytes to endothelial cells is mediated by PfEMP1 and is encoded by a *var* gene and that 2) Su et al. has taught that *var* genes encode 200-350 kDa proteins in *P. falciparum* it would have been *prima facie* obvious of one of ordinary skill in the art at the time of the invention to combine the teachings of Rowe and Su et al. One would have been motivated to characterize proteins encoded by *var* in view of the teachings of Rowe et al. that that such proteins are potential parasite ligands.

5. Claims 13 and 21 and 23 rejected under 35 U.S.C. 103(a) as being unpatentable over Rowe et al. in view of Baruch et al. is **maintained**. This rejection is further applied to claims 33-38.

Applicant's have asserted that Rowe et al. does not teach the polypeptide claimed by the Applicant. Applicant's have further asserted Baruch et al. also teaches of a different polypeptide malarial medicament with only some of the same characteristics of the polypeptide in the instant invention .

Applicant's arguments have been carefully considered but not deemed persuasive.

The claims are drawn to a malarial medicament comprising a PfEMP1 fusion protein.

Baruch et al. teach of a malarial medicament comprising a PfEMP1 fusion protein.

Given that 1) Rowe et al. has taught of a malaria erythrocyte membrane protein and that 2) Baruch et al. has taught of a malarial medicament comprising a PfEMP1 fusion protein it would have been *prima facie* obvious of one of ordinary skill in the art at the time of the invention to make a malarial medicament comprising a PfEMP1 fusion protein. One would have been motivated to make a malarial medicament in view of the teachings of Baruch et al. that the binding sites on PfEMP1 and cognate host cell receptors could be used in developing agents for the reversal of *P. falciparum* parasitized erythrocytes adherence and consequent occlusion of microvessels.

***New Grounds for Rejection based on Amendment***

***Claim Rejections - 35 USC § 112***

6. Claims 16, and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 is vague and indefinite in the recitation of "essentially specific".

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One of skill in the art would be unable to determine the metes and bounds of the limitations. Without a clear definition as to what constitutes "essentially specific" binding one of skill in the art would be unable to replicate the claim.

Claim 36 is vague and indefinite in the recitation of "an analogue". One of skill in the art would be unable to determine the metes and bounds of the limitations. Without a clear definition as to what constitutes as an "analog" of SEQ ID NO:1 one of skill in the art would be unable to replicate the claim.

### **Status of Claims**

7. All claims stand rejected.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any



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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

For the above reasons, it is believed that the rejections should be sustained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iesha P Fields whose telephone number is (703) 605-1208. The examiner can normally be reached on 7am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



**MARK NAVARRO**  
PRIMARY EXAMINER

Iesha Fields

October 17, 2001